FDAMA STAKEHOLDER MEETING
APRIL 28, 1999
Talking with Stakeholders About FDA Modernization

✓ Site: Boston, MA

**Your question/comments will become part of Docket Number: 99N-0386
Fax to: 1-888-361-4011 (on April 28 only)

Title (required) ☐Dr. ☒Mr. ☐Mrs. ☐Ms.
First Name (required) Dave
Last Name (required) Fleming
Organization Genzyme Corporation

Stakeholder Group ✓ stakeholder group you represent

☐ Consumer ☐ Consumer Group ☐ Health Professional ☑ Industry ☐ Association ☐ Other

Center ✓ the center/product area your comments address

☐ Center for Biologics Evaluation and Research
☐ Center for Devices and Radiological Health
☐ Center for Veterinary Medicine
☑ FDA General
☐ Center for Drug Evaluation and Research
☐ Center for Food Safety and Applied Nutrition
☐ Office of Regulatory Affairs

Questions to Stakeholders

Please check the box next to the stakeholder question/s from the March 22, 1999, Federal Register notice which your question/comment addresses.

☐ 1. What actions do you propose the Agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision-making?
☐ 2. What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's life cycle?
☐ 3. What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?
☐ 4. What actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?
☐ 5. What additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?
☐ 6. Additional Comments on FDA Modernization Efforts.

YOUR COMMENT/QUESTION

Dr Henney,
Could you please define the types of user fees that you envision for medical devices (eg submission fees, establishment fees, product fees).
Also how would these fees be used by the FDA? Only for product review or also for other purposes such as post market surveillance.

Thank you C17

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